1:3, and the weight ratio of said surfactant to said polyvinylpyrrolidone is about 10:1 to about 1:1.

Remarks

This paper is in response to the official action of January 13, 2003 wherein claims 1-20 and 25-27 over WO 96/03113 (WO '113) in view of Hauer, Hauer in view of WO '113, and Hauer in view of WO 99/49848. This response is timely filed, as it is accompanied by a petition for automatic extension of time to file in the second month, and the requisite extension fee.

By the foregoing, claim 1 has been amended to modify the description of the subject matter of the invention, claim 5 has been canceled in view of the inclusion in claim 1 of the limitation of claim 5, and claim 2 has been amended in view of the amendment to claim 1.

Claim 1 and those claims dependent therefrom, were rejected allegedly since "it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to add PVP of Hauer, as a thickening agent." (official action at 4) The obviousness rejection of claims 1-20 and 25-27 over WO 96/03113 (WO '113) in view of Hauer, Hauer in view of WO '113, and Hauer in view of WO 99/49848 is respectively traversed. Reconsideration is requested.

Hauer teaches the use of PVP as a thickening agent and lists specific examples of high molecular weight PVP for use as thickening agents. Hauer at column 12, line 66 to column 13, line 6. Hauer does not teach using PVP other than as a thickening agent, and specifically does not teach the use of low molecular weight PVP (*e.g.*, in the range of about 2,500 to about 20,000) to achieve the dissolution of a highly lipophilic active agent.

The rejection of claims 1-20 and 25-27 is believed to be overcome by the amendment of independent claims 1 to incorporate a limitation to low molecular weight

polyvinylpyrrolidone (PVP). With low molecular weight PVP, the recited self-emulsifying drug delivery system is only using PVP to achieve the dissolution of the active agent, not as a thickening agent as taught in Hauer. Specification at page 7, line 31 to page 8, line 8.

The recited formulation provides a high oral bioavailability in the administration of an extremely water-insoluble active agent. Specification at page 16, lines 1 to 11. The low molecular weight PVP improves the solubility of the water-insoluble active agent, and thereby allows for more of the active agent to be available for therapeutic use. Specification at page 8, lines 1-8. With higher molecular weight PVP, the PVP only thickens the formulation and does not act to improve on the solubility of the active agent.

In view of the foregoing, it is submitted that claims 1-20 and 25-27 are in proper form for allowance, and such action is solicited.

It also appears from a review of the papers received with the official action, that page 2 of the reviewed Form PTO—1449 filed on October 23, 2001, was inadvertently not attached to the official action. Applicants respectfully request the submission of reviewed page 2 of 3 of the Form PTO—1449 filed on October 23, 2001.

Should the examiner wish to discuss the foregoing or any matter of form in an effort to advance this application toward allowance, he is urged to telephone the undersigned at the indicated number.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Please amend claims 1 and 2 as follows:

1. (Twice Amended) A self-emulsifying drug delivery system comprising a mixture of an extremely water-insoluble, lipophilic active agent; polyvinylpyrrolidone; a fatty acid; and a surfactant,[wherein the weight ratio of said fatty acid to said polyvinylpyrrolidone is about 2:1 to about 1:3] wherein the polyvinylpyrrolidone has a molecular weight of about 2,500 to about 20,000.

2. (Twice Amended) The self-emulsifying drug delivery system of claim 1, wherein the weight ratio of said fatty acid to said polyvinylpyrrolidone is about 2:1 to about 1:3, and the weight ratio of said surfactant to said polyvinylpyrrolidone is about 10:1 to about 1:1.

Please cancel claim 5, without prejudice.